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EXAMINER	
TATE, CHRISTOPHER ROBIN	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/528,500	DE MORAES BARROS ET AL.	
	Examiner	Art Unit	
	Christopher R. Tate	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 September 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *14-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The amendment filed 24 September 2007 is acknowledged and has been entered. Claims 14-23 have been examined on the merits. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

Claims 14-23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 14, 18, and 19, as instantly amended, now recite the range of 4-nerolidylcatechol as being from "2.1 to 20%" which is deemed new matter as the Examiner could find nowhere within the instant disclosure (including the original claims) which support the lower range limit of 2.1%. That is, as originally claimed and disclosed by the instant specification, the amount range of 4-nerolidylcatechol within the extract/composition is taught to be from 0.005% to 20% (not from 2.1% to 20% as instantly claimed). In addition, please note that the instantly demonstrated examples of such a composition (e.g., topically applied to hairless mice) was a gel extract composition comprising 0.1% 4-nerolidylcatechol (see, e.g., Examples 1 and 2 as shown on pages 13-18 of the instant specification). Accordingly, the recited instantly claimed narrower range amount thereof ("2.1 to 20.0%") is not supported by the instant specification and, thus, is deemed new matter.

All other claims depend directly or indirectly from rejected claims and are, therefore, also rejected under USC 112, first paragraph for the reasons set forth above.

Applicant is required to cancel the new matter in the reply to this Office Action - or alternatively, to particularly point to adequate support for this newly recited amount range, in response to this Office action.

Applicants' arguments as they pertain to the above rejection have been carefully considered but are not deemed to be persuasive of error in the rejection. Applicants argue that the upper limit has been amended so as to now recite "20.0%". However, the above rejection pertains the new matter limitation brought about by the instantly amended lower limit recitation of "2.1%".

In addition, as set forth in the previous Office action, the instant specification fails to provide an adequate written description with respect preparing a standardized extract of *Pothomorphe umbellata* which when added to a composition provides an overall composition containing the instantly claimed ranges of 4-nerolidylcatechol (on the basis of the standardized extract) therein. That is, the specification appears to be silent in terms of describing to one of skill in the art how to make the instantly claimed standardized extract of *Pothomorphe umbellata* as it relates to an overall composition containing 2.1 to 20.0% of 4-nerolidylcatechol (in the form of the extract) therein. It should be noted that the instant specification alludes to the fact that the antioxidant activity demonstrated by various prior art *Pothomorphe umbellata* extract

preparations may be due to not just to the compound 4-nerolidylcatechol, but also to the presence of other additional compounds within such extract preparations that contribute to their observed enhanced antioxidant activity - as compared to the antioxidant activity displayed by the isolated compound 4-nerolidylcatechol alone (see, e.g., page 6, line 25 - page 7, line 5 of the instant specification) - which would also suggests that the steps by which the recited "standardized extract" is prepared would necessarily be essential in terms of making a standardized extract of *Pothomorphe umbellata* for incorporation into an overall composition containing the recited percentage range of 4-nerolidylcatechol (contained within the standardized extract) therein (as instantly claimed) - including with respect to its functional (enhanced antioxidant) ability to treat the various skin afflictions instantly claimed (further, without this information, how would the skilled artisan properly compare/distinguish prior art *Pothomorphe umbellata* extract preparations from the instantly claimed *Pothomorphe umbellata* extract preparation? - see art rejections below for additional information).

Accordingly, the instant specification lacks an adequate written description as to the essential extraction steps necessary to actually prepare a "standardized extract of *Pothomorphe umbellata*" which contains the instantly claimed ranges of 4-nerolidylcatechol therein (and, thus, claims 14-23 lack an adequate written description with respect to the instantly claimed "standardized extract of *Pothomorphe umbellata*" for the reasons discussed above).

Applicants' arguments concerning the rejection immediately above have been carefully considered but are not deemed to be persuasive of error in the rejection. Applicants argue that the specification teaches various aspects of the claimed invention within a number of cited

paragraphs including that it can be obtained via numerous preparatory techniques including (as disclosed in instant paragraph [0036]) a high efficiency chromatography device coupled to an electrochemistry detector or UV detector, or through any known methods in the pharmacy art (as disclosed in instant paragraphs [0037] and [0039]). Applicants also argue that although the specification does not lay out the process step by step, one of ordinary skill in the art does not need to have these methods of preparing the composition explicitly spelled out step by step. However, these arguments are not deemed persuasive for the reasons fully set forth in the above rejection - i.e., the instant specification fails to provide an adequate written description with respect preparing a standardized extract of *Pothomorphe umbellata* which when added to a composition provides an overall composition containing the instantly claimed ranges of 4-nerolidylcatechol (on the basis of the standardized extract) therein. Applicants also argue that the Examiner's comments regarding the antoxidant activity of the other compounds possibly found in *Pothomorphe umbellata* extracts is irrelevant with regard to 35 USC 112, first paragraph, including because the efficacy of the present invention relies specifically on the use of *Pothomorphe umbellata* extract with a 4-nerolidylcatechol concentration of 0.005% to 20%, which one of skill in the art would be able to make. However, as discussed in the previous Office action and above, the instant specification alludes to the fact that the antioxidant activity demonstrated by various prior art *Pothomorphe umbellata* extract preparations may be due to not just to the compound 4-nerolidylcatechol, but also to the presence of other additional compounds within such extract preparations that contribute to their observed enhanced antioxidant activity - as compared to the antioxidant activity displayed by the isolated compound 4-nerolidylcatechol alone (see, e.g., page 6, line 25 - page 7, line 5 of the instant specification) - which would also

suggests that the steps by which the recited "standardized extract" is prepared would necessarily be essential in terms of making a standardized extract of *Pothomorphe umbellata* for incorporation into an overall composition containing the recited percentage range of 4-nerolidylcatechol (contained within the standardized extract) therein (as instantly claimed) - including with respect to its functional (enhanced antioxidant) ability to treat the various skin afflictions instantly claimed (further, without this information, how would the skilled artisan properly compare/distinguish prior art *Pothomorphe umbellata* extract preparations from the instantly claimed *Pothomorphe umbellata* extract preparation? In addition, Applicants arguments concerning the percentage range of 4-nerolidylcatechol (0.005-20%) within their *Pothomorphe umbellata* extract is inconsistent with the instant claim language - i.e., the instant claims (although unclear - as discussed below under USC 112, second paragraph) instead are apparently defining the instantly recited percentage range of 4-nerolidylcatechol (2.1-20%) within the overall composition, not the percentage of 4-nerolidylcatechol within the extract itself.

Claims 14-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 14 remains vague and indefinite by the phrase "a standardized extract of *Pothomorphe umbellata* which contains a range from 2.1-20.0% by weight of 4-nerolidylcatechol in the composition". Based upon the lack of written description concerning the instantly claimed extract (as discussed in detail above) it is unclear as to the actual meaning of

this limitation - i.e., what type of extract (including in terms of standardization) is this actually defining (e.g., an alcoholic extract or something else)?

Claim 14 is also rendered exceedingly vague and indefinite by the overall phrase "A composition containing *Pothomorphe umbellata* extract comprising a standardized extract of *Pothomorphe umbellata* which contains a range from 2.1 to 20.0% by weight of 4-nerolidylcatechol in the composition". This overall phrase is very unclear and confusing firstly because this phrase would imply that the *Pothomorphe umbellata* extract contains another extract of itself therein - i.e., a standardized extract of *Pothomorphe umbellata* within the first recited extract thereof. Secondly, it is unclear if the recited percentage range of 4-nerolidylcatechol is the percentage by weight within the first recited extract, within the standardized extract, or within the overcall composition (e.g., an overall cosmetic composition comprising the extract/standardized extract).

Claims 15-17 remain vague and indefinite by the phrase "said composition is presented for ...". It is unclear as to how and in what way such a composition is "presented" - e.g., is the composition actually in the form of gel or is it merely presented in some form for future incorporation into a gel?

Claim 20 remains vague and indefinite by the phrase "topically administered in a way to allow satisfactory therapeutic response" (lines 3-4). It is unclear by this exceedingly ambiguous phrase as to what type of therapeutic response is being defined/envisioned (e.g., is the therapeutic response such that the skin becomes moisturized, UV-protected, less damaged?).

Claims 21-23 remain vague and indefinite by the phrase "comprising an ...activity" because these claims depend from the method of claim 20. Accordingly, it is unclear as to the

context of this phrase - e.g., is the composition administered in an amount to provide the recited activities, does the extract within the composition have the recited activities, or something else?

All other claims depend directly or indirectly from rejected claims and are, therefore, also rejected under USC 112, second paragraph for the reasons set forth above.

Applicants' arguments as they pertain to the USC 112, second paragraph rejections immediately above have been carefully considered but are not deemed to be persuasive of error in the rejections. Applicants argue that the claims have been amended to facilitate prosecution. However, the claims remain vague and indefinite for the reasons fully set forth above.

Claim Rejections - 35 USC § 102

Claims 14-17 and 20-23 stand rejected under 35 U.S.C. 102(b) as being anticipated by Ropke et al. (Annals of the 14th National Cosmetology Congress of the Brazilian Cosmetology Assoc, 2000 - Entire English Translation of this document also enclosed).

The cited reference teaches a topical compositions presented in a gel form (i.e., within diadermine - an oil/water emulsion) comprising an extract of *Pothomorphe umbellata*, whereby the topical compositions comprises 0.2%, 0.05, 0.1, 0.2, and 2% (p/p) of 4-nerolidylcatechol therein. Ropke et al. also teach that the dry extract contains 2.35% of 4-nerolidylcatechol therein (see, e.g., page 8 of English translation). This reference also teaches topically applying the topical compositions to the skin of hairless mice (see entire English translation including pages 2-5, 7-9, 13-14, 16, and final paragraph on page 18). Please note that the topical application of the reference extract topical preparation would inherently provide one or more of

the functional effects instantly claimed, including with respect to preventing such skin afflictions. In addition, please note that due to the indefiniteness of claim 14 with respect to what the percentage range "2.1%-20.0% by weight 4-nerolidylcatechol" is actually defining (i.e., as set forth above, it is unclear if this percentage range is attempting to define the percentage of 4-nerolidylcatechol within the first recited extract, within the standardized extract, or within the overall composition), the upper percentage expressly taught by Ropke et al. (2.0% p/p), as well as the amount within the dry extract (2.35%), are deemed to reasonably read upon the instantly recited lower percentage range level (as best understood).

Therefore, the cited reference is deemed to anticipate the instant claims above.

Applicants' arguments concerning the art rejection immediately above have been carefully considered but are not deemed to be persuasive of error in the rejection. Applicants argue that the current set of claims overcomes the above rejection since Ropke et al. do not teach or suggest the limitation of 2.1 to 20.0% by weight of 4-nerolidylcatechol. However, as discussed above, the upper percentage expressly taught by Ropke et al. (2.0% p/p), as well as the amount within the dry extract (2.35%), are deemed to reasonably read upon the instantly recited lower percentage range level (as best understood).

Claim Rejections - 35 USC § 102/103

Claims 14 and 15 stand rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Barros et al. (Ciencia e Cultura, 1996) or over Desmarchelier et al. (Planta Med, 1997).

Each of the cited references teaches a composition comprising an alcoholic (ethanolic - Barros et al; methanolic - Desmarchelier et al) extract of *Pothomorphe umbellata* having strong antioxidant activity (such as instantly disclosed) which each reference expressly discloses contain the compound 4-nerolidylcatechol - apparently within the instantly claimed percentage range (as best understood) - therein (see entire documents). Please note that given the lack of guidance (written description) provided by the instant specification in terms of making the instantly claimed *Pothomorphe umbellata* extract (as discussed above), the reference extract compositions each appear to be the same as that instantly claimed (as best understood). Consequently, the claimed *Pothomorphe umbellata* extract appears to be anticipated by each of the cited references.

In the alternative, even if the claimed *Pothomorphe umbellata* extract is not identical to the referenced *Pothomorphe umbellata* extracts with regard to some unidentified characteristics, the differences between that which is disclosed and that which is claimed are considered to be so slight that the referenced *Pothomorphe umbellata* extracts are likely to inherently possess the same characteristics of the claimed *Pothomorphe umbellata* extract particularly in view of the similar characteristics which they have been shown to share. Thus, the claimed *Pothomorphe umbellata* extract would have been obvious to those of ordinary skill in the art within the meaning of USC 103.

Accordingly, the claimed invention as a whole was at least *prima facie* obvious, if not anticipated by the reference, especially in the absence of sufficient, clear, and convincing evidence to the contrary.

Applicants' arguments concerning the USC 102/103 rejections immediately above have been carefully considered but are not deemed to be persuasive of error in the rejections. Applicants argue that neither of the cited references teaches or suggests the limitation of 2.1-20% by weight of 4-nerolidylcatechol. However, as discussed above, each of the cited references teaches a composition comprising an alcoholic (ethanolic - Barros et al; methanolic - Desmarchelier et al) extract of *Pothomorphe umbellata* having strong antioxidant activity (such as instantly disclosed) which each reference expressly discloses contain the compound 4-nerolidylcatechol - apparently within the instantly claimed percentage range (as best understood) - therein (see entire documents). Please note that given the lack of guidance (written description) provided by the instant specification in terms of making the instantly claimed *Pothomorphe umbellata* extract (as discussed above), the reference extract compositions each appear to be the same as that instantly claimed (as best understood). Further, as discussed above - in the alternative, even if the claimed *Pothomorphe umbellata* extract is not identical to the referenced *Pothomorphe umbellata* extracts with regard to some unidentified characteristics, the differences between that which is disclosed and that which is claimed are considered to be so slight that the referenced *Pothomorphe umbellata* extracts are likely to inherently possess the same characteristics of the claimed *Pothomorphe umbellata* extract particularly in view of the similar characteristics which they have been shown to share. Thus, the claimed *Pothomorphe*

umbellata extract would have been obvious to those of ordinary skill in the art within the meaning of USC 103. Applicants did not provide any objective evidence showing an unobvious difference between the claimed extract composition and those disclosed by the cited references - including objective evidence showing that the extracts taught by the cited references do not comprise the claimed percentage range of 4-nerolidylcatechol therein.

Claims 14, 15, and 20-23 stand rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Uchiyama et al. (JP 2001122763 - full computer-assisted English translation enclosed) - with evidence provided by Barros et al. (Ciencia e Cultura, 1996) and Desmarchelier et al. (Planta Med, 1997)*.

Uchiyama et al. teach a topical skin composition comprising an extract of *Pothomorphe umbellata* (including an alcoholic extract such as an ethanolic or methanolic extract - please note, as evidenced by Barros et al. and Desmarchelier et al., such an alcoholic extract would inherently comprise the naturally-occurring compound 4-nerolidylcatechol - see entire documents) as an active skin therapeutic ingredient therein (e.g., useful against skin aging caused by ultraviolet rays among other therapeutic effects), as well as topically applying such a composition to the skin (please also note that topical application of the reference *Pothomorphe umbellata* extract would inherently prevent the recited skin afflictions, as instantly claimed), including applying to human skin fibroblasts. Uchimyama et al. also teach that the extract composition has antioxidant activity (i.e., oxygen-eliminating ability) - such as instantly disclosed (see entire English translation including paragraphs [0007] - [0016], [0021], [0028], [0034]-0035], [0037], and Tables). Again, please note that given the lack of guidance (written

description) provided by the instant specification in terms of making the instantly claimed *Pothomorphe umbellata* extract (as discussed above), the reference extract composition appears to be the same as that instantly claimed (as best understood). Consequently, the claimed *Pothomorphe umbellata* extract appears to be anticipated by the cited reference.

In the alternative, even if the claimed *Pothomorphe umbellata* extract is not identical to the referenced *Pothomorphe umbellata* extract with regard to some unidentified characteristics, the differences between that which is disclosed and that which is claimed are considered to be so slight that the referenced *Pothomorphe umbellata* extract is likely to inherently possess the same characteristics of the claimed *Pothomorphe umbellata* extract particularly in view of the similar characteristics which they have been shown to share. Thus, the claimed *Pothomorphe umbellata* extract would have been obvious to those of ordinary skill in the art within the meaning of USC 103.

Accordingly, the claimed invention as a whole was at least *prima facie* obvious, if not anticipated by the reference, especially in the absence of sufficient, clear, and convincing evidence to the contrary.

With respect to the USC 102/103 rejections above, please note that the Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether Applicants' *Pothomorphe umbellata* extract differs (especially given that the instant specification fails to teach how to make the instantly claimed standardized extract) and, if so, to what extent, from the discussed references. Therefore, with the showing of the references, the burden of establishing non-obviousness by objective evidence is shifted to the Applicants.

* Please note that the Barros et al. and Desmarchelier et al. references cited in the USC 102/103 rejection immediately above are not being cited as prior art, but rather as evidence to show an inherent property of the *Pothomorphe umbellata* extract taught by Uchiyama et al. (i.e., that the alcoholic extract taught by Uchiyama et al. inherently contains the naturally-occurring compound 4-nerolidylcatechol therein).

Applicants' arguments concerning the USC 102/103 rejection above have been carefully considered but are not deemed to be persuasive of error in the rejection. Applicants argue that a translation must be obtained so that the record is clear as to the precise facts the Examiner is relying upon. Thus, although the Examiner included a computer-assisted translation of Uchiyama et al., the translation fails to disclose all of the relevant facts and information in English (including a full translation of the Tables) and therefore the Uchiyama et al. reference may not be cited as prior art However, the Examiner relied upon the teachings provided by the computer-assisted English translation of Uchiyama et al. (which is a totally acceptable practice within the USPTO with respect to providing an English translation thereof, and thus may be relied upon as prior art) including with regard to providing the necessary teachings (including those provided by the Tables therein) to one of ordinary skill in the art. Accordingly, for the reasons fully set forth above, the Uchiyama et al. reference is deemed to teach and/or suggest the instantly claimed invention.

Claim Rejections - 35 USC § 103

Claims 14-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ropke et al. (Free Radical Biol. Med., Vol 33, Issue 2, Abstract #527, 15 July 2002) and Ropke et al. (Annals of the 14th National Cosmetology Congress of the Brazilian Cosmetology Assoc, 2000 - Entire English Translation of this document also enclosed, in view of Wheeler (US 6,165,479) and, if necessary, the admitted state of the art.

The two cited Ropke et al. references each beneficially teach a topical gel compositions having strong therapeutic antioxidant activity which comprises an extract of *Pothomorphe umbellata*, whereby the gel compositions comprises 4-nerolidylcatechol (on the basis of the *Pothomorphe umbellata* extract). In addition, as discussed *supra*, the second Ropke et al. reference (2000) discloses a topical compositions presented in a gel form (i.e., within diadermine - an oil/water emulsion) comprising an extract of *Pothomorphe umbellata*, whereby the topical compositions comprises 0.2%, 0.05, 0.1, 0.2, and 2% (p/p) of 4-nerolidylcatechol therein; and further that the dry extract contains 2.35% of 4-nerolidylcatechol therein (see, e.g., page 8 of English translation) - thus, apparently within the instantly claimed ranges therein (as best understood). The cited Ropke et al. references also teach topically applying the gel compositions to the skin of hairless mice (see Abstract# S527 of first Ropke et al. reference; and entire English translation including pages 2-5, 7-9,13-14, 16, and final paragraph on page 18 of the second Ropke et al. reference). Neither of the Ropke et al. references expressly teach providing the skin therapeutic *Pothomorphe umbellata* extract within a skin gel composition containing carboxymethylcellulose, propylene glycol, and methylparaben, as instantly claimed.

Wheeler beneficially teaches that carboxymethylcellulose, propylene glycol, and methylparaben are well known conventional ingredients within skin therapeutic compositions such as skin gels, including those containing an antioxidant therein (see entire reference, including col 2, line 58 - col 4, line 67). Further, as readily admitted by Applicants, the instantly claimed dermocosmetic composition can be prepared in accordance with prior art methods for topical use - such as one containing carboxymethylcellulose, propylene glycol, and methylparaben (see, e.g., page 11, lines 1-5).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to incorporate the *Pothomorphe umbellata* extract preparation having strong therapeutic antioxidant activity as taught by each of the Ropke et al. references into a conventional skin therapeutic formulation (e.g., as an effective antioxidant) - including a skin gel, containing the commonly-employed skin care ingredients carboxymethylcellulose, propylene glycol, and methylparaben therein based upon the beneficial teachings provided by Wheeler, as well as (if necessary) the admitted state of the prior art, with respect to their well known conventional use therein, as discussed above. Accordingly, the adjustment of this and other types of conventional working conditions (e.g., determining an appropriate amount range of such conventional ingredients therein) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan. Please note that the topical application of such an extract gel preparation would intrinsically provide one or more of the functional effects instantly claimed, including with respect to preventing such skin afflictions.

Thus, the invention as a whole was clearly *prima facie* obvious over the references (and, if necessary, the admitted state of the art) especially in the absence of evidence to the contrary.

Applicants' arguments concerning the art rejection immediately above have been carefully considered but are not deemed to be persuasive of error in the rejection. Applicants again argue that neither of the Ropke et al. reference teach or suggest a range of 2.1 to 20% 4-nerolidylcatechol therein. However, as discussed above, the second Ropke et al. reference (2000) expressly discloses a topical compositions presented in a gel form (i.e., within diadermine - an oil/water emulsion) comprising an extract of *Pothomorphe umbellata*, whereby the topical compositions comprises 0.2%, 0.05, 0.1, 0.2, and 2% (p/p) of 4-nerolidylcatechol therein; and further that the dry extract contains 2.35% of 4-nerolidylcatechol therein (see, e.g., page 8 of English translation) - thus, apparently within the instantly claimed ranges therein (as best understood). Applicants further argue that Wheeler teaches that carboxymethylcelluose, propylene glycol, and methylparaben may be used in the aqueous phase of a composition which also contains a bi-liquid foam and, thus, a combination of either the Ropke et al. references and Wheeler would not form the presently claimed invention. However, Applicants arguments regarding such limitations are not commensurate to language defining the instantly claimed invention (see, e.g., instant claim 14). In addition, as discussed above, Wheeler was relied upon within the USC 103 rejection above essentially because this reference beneficially teaches that carboxymethylcellulose, propylene glycol, and methylparaben are well known conventional ingredients within skin therapeutic compositions such as skin gels, including those containing an antioxidant therein (see entire reference including col 2, line 58 - col 4, line 67). Further, as

readily admitted by Applicants, the instantly claimed dermocosmetic composition can be prepared in accordance with prior art methods for topical use - such as one containing carboxymethylcellulose, propylene glycol, and methylparaben (see, e.g., page 11, lines 1-5). Applicants did not make any arguments toward the admitted state of the art.

Claims 14-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Uchiyama et al. (JP 2001122763 - full computer-assisted English translation enclosed) in view of Barros et al. (Ciencia e Cultura, 1996) and Desmarchelier et al. (Planta Med, 1997), and further in view of Wheeler (US 6,165,479) and, if necessary, the admitted state of the art.

Uchimyama et al. beneficially teach a topical skin composition (e.g., in the form of a lotion, cream, etc.) comprising an extract of *Pothomorphe umbellata*.(including an alcoholic extract such as an ethanolic or methanolic extract - please note, as evidenced by Barros et al. and Desmarchelier et al., such an alcoholic extract would inherently comprise the naturally occurring compound 4-nerolidylcatechol) as an active skin therapeutic ingredient therein (e.g., useful against skin aging caused by ultraviolet rays among other therapeutic effects), as well as topically applying such a composition to the skin. Uchimyama et al. also beneficially teach that the extract composition has antioxidant activity (i.e., oxygen-eliminating ability) - such as instantly disclosed (see entire English translation including paragraphs [0007] - [0016], [0021], [0028], [0034]-0035], [0037], and Tables).

The Barros et al. and Desmarchelier et al. references each beneficially teach a composition comprising an alcoholic (ethanolic - Barros et al; methanolic - Desmarchelier et al) extract of *Pothomorphe umbellata* - whereby the extracts demonstrate strong antioxidant activity

(such as instantly disclosed) which contain the compound 4-nerolidylcatechol - apparently within the instantly claimed percentage range (as best understood) - therein (see entire documents including *Abstract* and *Materials and Methods*).

None of the above references, including Uchimyama et al., expressly teach providing the skin therapeutic *Pothomorphe umbellata* extract within a skin gel composition - including one containing carboxymethylcellulose, propylene glycol, and methylparaben, as instantly claimed.

Wheeler beneficially teaches that carboxymethylcellulose, propylene glycol, and methylparaben are well known conventional ingredients within skin therapeutic compositions such as skin gels, including those containing an antioxidant therein (see entire reference including col 2, line 58 - col 4, line 67). Further, as readily admitted by Applicants, the instantly claimed dermocosmetic composition can be prepared in accordance with prior art methods for topical use - such as one containing carboxymethylcellulose, propylene glycol, and methylparaben (see, e.g., page 11, lines 1-5).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to incorporate an alcoholic (e.g., ethanolic or methanolic) extract of *Pothomorphe umbellata* within the skin therapeutic composition (having antioxidant activity) as taught by Uchimyama et al, especially since Uchimyama et al. beneficially teaches that ethanolic and methanolic solvents are effective solvents to employ, and Barros et al. and Desmarchelier et al. beneficially teaches that such alcoholic solvents provide a *Pothomorphe umbellata* extract having strong antioxidant activity (in addition, it should again be noted that, as evidenced by Desmarchelier et al., such an alcoholic extract would inherently comprise the naturally-occurring compound 4-nerolidylcatechol therein). It would further have been obvious to one of ordinary

skill in the art at the time the claimed invention was made to incorporate such a *Pothomorphe umbellata* extract into a conventional skin therapeutic formulation (e.g., as an effective antioxidant) - including a skin gel, containing the commonly-employed skin care ingredients carboxymethylcellulose, propylene glycol, and methylparaben therein based upon the beneficial teachings provided by Wheeler, as well as (if necessary) the admitted state of the prior art, with respect to their well known conventional use therein, as discussed above. Accordingly, the adjustment of this and other types of conventional working conditions (e.g., determining an appropriate amount range of such ingredients therein) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Thus, the invention as a whole was *prima facie* obvious over the references (and, if necessary, the admitted state of the art) especially in the absence of evidence to the contrary.

Applicants' arguments concerning the art rejection immediately above have been carefully considered but are not deemed to be persuasive of error in the rejection. Applicants again argue that a translation must be obtained so that the record is clear as to the precise facts the Examiner is relying upon. Thus, although the Examiner included a computer-assisted translation of Uchiyama et al., the translation fails to disclose all of the relevant facts and information in English (including a full translation of the Tables) and therefore the Uchiyama et al. reference may not be cited as prior art However, the Examiner relied upon the teachings provided by the computer-assisted English translation of Uchiyama et al. (which is a totally acceptable practice within the USPTO with respect to providing an English translation thereof, and thus may be relied upon as prior art) including with regard to providing the necessary

teachings (including those provided by the Tables therein) to one of ordinary skill in the art. Applicants further argue that neither Barros et al. nor Desmarchelier et al. teach the limitation of a range of 2.1 to 20.0% 4-nerolidylcatechol therein. However, as discussed above, each of the cited references teaches a composition comprising an alcoholic (ethanolic - Barros et al; methanolic - Desmarchelier et al) extract of *Pothomorphe umbellata* having strong antioxidant activity (such as instantly disclosed) which each reference expressly discloses contain the compound 4-nerolidylcatechol - apparently within the instantly claimed percentage range (as best understood). Further, Applicants did not provide any objective evidence showing an unobvious difference between the claimed extract composition and those disclosed by the cited references - including objective evidence showing that the extracts taught by Barros et al. or Desmarchelier et al. references do not comprise the claimed percentage range of 4-nerolidylcatechol therein. Although Applicants did not make any arguments toward the Wheeler reference or toward admitted state of the art with respect to the USC 103 rejection immediately above, Applicants have argued and discussed the other cited references individually without clearly addressing the combined teachings. It must be remembered that the references (as well as the admitted state of the art) are relied upon in combination and are not meant to be considered separately as in a vacuum. It is the combination of all of the cited and relied upon references (as well as the admitted state of the art) which make up the state of the art with regard to the claimed invention. Applicant's claimed invention fails to patentably distinguish over the state of the art represented by the references (and admitted state of the art).

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Conclusion

No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to Applicants' disclosure. **In addition (if not already cited by the Examiner within the previous Notice of References: PTO-892), it is again requested that Applicants provide a copy of the prior art references cited in the paragraph bridging pages 6-7 of the instant specification in response to this Office action (the Examiner was unable to obtain at least some of the discussed references therein, due to the limited information provided within this paragraph) as these prior art references also appear pertinent to Applicants' disclosure (the 1999 reference by ROPKE concerning the topical application of an extract of *Pothomorphe umbellata* roots to the skin of hairless mice would appear to be particularly pertinent).**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher R. Tate whose telephone number is (571) 272-0970. The examiner can normally be reached on Mon-Thur, 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Christopher R. Tate
Primary Examiner
Art Unit 1655